

FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 08/405,454	ATTY. DOCKET NO.: P0786.70000US05
		FILING DATE: March 15, 1995	CONFIRMATION NO.:
		APPLICANT: John B. Sullivan et al.	
		GROUP ART UNIT: 1644	EXAMINER: R. B. Schwadron
Sheet 1 of 5 JUN 30 2010 TRADEMARK OFFICE			

#### U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		4,012,502		Philpot	03-15-1977
		4,742,159		Batz et al.	05-03-1988
		4,849,352		Sullivan et al.	07-08-1989
		5,256,409		Blincko	10-26-1993

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

#### OTHER ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		[No Author Listed] British National Formulary. 1974-6. p. 34.	
		[No Author Listed] Dorland's Medical Dictionary, 26 <sup>th</sup> Ed. W.B. Saunders Company. 1981, p 1449.	
		[No Author Listed] WHO Coordination Meeting on Venoms and Antivenoms. WHO/B5/80-1292 BLG/ver/80.1 Rev. 1. September 24-27, 1979. 1 page.	
		AUDEBERT et al., Pharmacokinetics of Vipera aspis venom after experimental envenomation in rabbits. J Pharmacol Exp Ther. 1994 Mar;268(3):1512-7.	
		BALTHASAR et al., Utilization of antidrug antibody fragments for the optimization of intraperitoneal drug therapy: studies using digoxin as a model drug. J Pharmacol Exp Ther. 1994 Feb;268(2):734-9.	
		BIRRELL et al., Molecular diversity in venom from the Australian Brown snake, Pseudonaja textilis. Mol Cell Proteomics. 2006 Feb;5(2):379-89. Epub 2005 Nov 10.	
		BON, The natural toxins. Biochimie. 2000 Sep-Oct;82(9-10):791-2.	
		BUTLER et al., Effects of sheep digoxin-specific antibodies and their Fab fragments on digoxin pharmacokinetics in dogs. J Clin Invest. 1977 Feb;59(2):345-59.	
		BUTLER, Antibodies as specific antagonists of toxins, drugs, and hormones. Pharmacol Rev. 1982 Mar;34(1):109-14.	
		CALDERÓN-ARANDA et al., Pharmacokinetics of the toxic fraction of Centruroides limpidus limpidus venom in experimentally envenomed rabbits and effects of immunotherapy with specific F(ab') <sub>2</sub> . Toxicon. 1999 May;37(5):771-82.	
		CHIPPAUX et al., Producers of antivenomous sera. Toxicon. 1983;21(6):739-52.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 06/659,629, filed October 9, 1984 (now issued Patent No. 4,849,352), and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

<b>FORM PTO-1449/A and B (modified PTO/SB/08)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 08/405,454	ATTY. DOCKET NO.: P0786.70000US05
				FILING DATE: March 15, 1995	CONFIRMATION NO.:
				APPLICANT: John B. Sullivan et al.	
				GROUP ART UNIT: 1644	EXAMINER: R. B. Schwadron
Sheet	2	of	5		

		CHOUMET et al., Immunochemical analysis of a snake venom phospholipase A2 neurotoxin, crotoxin, with monoclonal antibodies. Mol Immunol. 1992 Jul-Aug;29(7-8):871-82.	
		CHOUMET et al., Neutralization of lethal potency and inhibition of enzymatic activity of a phospholipase A2 neurotoxin, crotoxin, by non-precipitating antibodies (Fab). FEBS Lett. 1989 Feb 13;244(1):167-73.	
		CHRISTENSEN, Problems of antivenene standardization revealed by the flocculation reaction. Bull World Health Organ. 1953;9(3):353-70.	
		CONSROE et al., Comparison of a new ovine antigen binding fragment (Fab) antivenin for United States Crotalidae with the commercial antivenin for protection against venom-induced lethality in mice. Am J Trop Med Hyg. 1995 Nov;53(5):507-10.	
		CORNEILLE et al., A large single-center experience with treatment of patients with crotalid envenomations: outcomes with and evolution of antivenin therapy. Am J Surg. 2006 Dec;192(6):848-52.	
	*	COULTER et al., Chem Abst. 1983 v.99 p3883.	
		DART et al., A randomized multicenter trial of crotalinae polyvalent immune Fab (ovine) antivenom for the treatment for crotaline snakebite in the United States. Arch Intern Med. 2001 Sep 10;161(16):2030-6.	
		DART et al., Affinity-purified, mixed monospecific crotalid antivenom ovine Fab for the treatment of crotalid venom poisoning. Ann Emerg Med. 1997 Jul;30(1):33-9.	
		DART et al., Effect of anti-desipramine Fab on desipramine toxicity in the rat. Veter Human Toxicol. Aug 1991;33(4):359. Abstract 31.	
		DART et al., Efficacy, safety, and use of snake antivenoms in the United States. Ann Emerg Med. 2001 Feb;37(2):181-8.	
		DART et al., Use of antibodies as antivenoms: a primitive solution for a complex problem? In Envenomings and Their Treatments. Eds. Bon et al. Proceedings of the 1 <sup>st</sup> Intl. Congress. Institut Pasteur, Paris, France. June 7-9, 1995. pp. 83-94.	
		DOS SANTOS et al., Purification of F(ab') <sub>2</sub> anti-snake venom by caprylic acid: a fast method for obtaining IgG fragments with high neutralization activity, purity and yield. Toxicon. 1989;27(3):297-303.	
		FAULSTICH et al., Strongly enhanced toxicity of the mushroom toxin alpha-amanitin by an amatoxin-specific Fab or monoclonal antibody. Toxicon. 1988;26(5):491-9.	
		FLANAGAN et al., Fab antibody fragments: some applications in clinical toxicology. Drug Saf. 2004;27(14):1115-33.	
		GAWADE et al., The use of antibody Fab fragments specifically directed to two different complementary parts of the tetanus toxin molecule for studying the mode of action of the toxin. Brain Res. 1985 May 13;334(1):139-46.	
		GODING, Use of staphylococcal protein A as an immunological reagent. J Immunol Methods. 1978;20:241-53	
		GUTIÉRREZ et al., Pharmacokinetic-pharmacodynamic relationships of immunoglobulin therapy for envenomation. Clin Pharmacokinet. 2003;42(8):721-41.	
		HARRIS et al., The effects of the subcutaneous injection of the crude venom of the Australian common brown snake, <i>Pseudonaja textiles</i> on the skeletal neuromuscular system. Br J Pharmac. 1981;73:157-63.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

# EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 06/659,629, filed October 9, 1984 (now issued Patent No. 4,849,352), and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 08/405,454	ATTY. DOCKET NO.: P0786.70000US05
				FILING DATE: March 15, 1995	CONFIRMATION NO.:
				APPLICANT: John B. Sullivan et al.	
				GROUP ART UNIT: 1644	EXAMINER: R. B. Schwadron
Sheet	3	of	5		

		HICKEY et al., Digoxin Immune Fab therapy in the management of digitalis intoxication: safety and efficacy results of an observational surveillance study. J Am Coll Cardiol. 1991 Mar 1;17(3):590-8.	
		HOLMES et al., Enhancement of monoclonal antibodies against HLA-A2 is due to antibody bivalency. J Biol Chem. 1983 Feb 10;258(3):1580-6.	
		JUCKETT et al., Venomous snakebites in the United States: management review and update. Am Fam Physician. 2002 Apr 1;65(7):1367-74.	
		KENIMER et al., Monoclonal antibodies as probes of tetanus toxin structure and function. Infect Immun. 1983 Dec;42(3):942-8.	
		KIRKPATRICK, Allergic histories and reactions of patients treated with digoxin immune Fab (ovine) antibody. The Digibind Study Advisory Panel. Am J Emerg Med. 1991 Mar;9(2 Suppl 1):7-10.	
	*	KOLB et al., Chem Abst. 1982, vol.97, p.90190s	
		KOLB et al., Cleavage of IgG by elastase-like protease (ELP) of human polymorphonuclear leukocytes (PMN): isolation and characterization of Fab and Fc fragments and low-molecular-weight peptides. Stimulation of granulocyte function by ELP-derived Fab and Fc fragments. Immunobiology. 1982 May;161(5):507-23. Abstract only.	
		KÖPPEL, Clinical symptomatology and management of mushroom poisoning. Toxicon. 1993 Dec;31(12):1513-40.	
		KRAVITZ et al., Copperhead snakebite treated with crotalidae polyvalent immune fab (ovine) antivenom in third trimester pregnancy. Clin Toxicol (Phila). 2006;44(3):353-4.	
		KRIFI et al., Pharmacokinetic studies of scorpion venom before and after antivenom immunotherapy. Toxicon. 2005 Feb;45(2):187-98.	
		LAING et al., Experimental assessment of a new, low-cost antivenom for treatment of carpet viper (Echis ocellatus) envenoming. Toxicon. 1995 Mar;33(3):307-13.	
		LAVONAS et al., Initial experience with Crotalidae polyvalent immune Fab (ovine) antivenom in the treatment of copperhead snakebite. Ann Emerg Med. 2004 Feb;43(2):200-6.	
		LEÓN et al., Comparative study on the ability of IgG and Fab sheep antivenoms to neutralize local hemorrhage, edema and myonecrosis induced by Bothrops asper (terciopelo) snake venom. Toxicon. 2000 Feb;38(2):233-44.	
		MADARAS et al., Antivenom development in Australia. Toxin Rev. 29 Mar 2005;24:79-94.	
		MAEDA et al., Isolation, properties and amino acid sequences of three neurotoxins from the venom of a sea snake, Aipysurus laevis. Biochem J. 1976 Jan 1;153(1):79-87.	
		MAYERS et al., Anti-immunoglobulin responses to IgG, F(ab') <sub>2</sub> , and Fab botulinum antitoxins in mice. Immunopharmacol Immunotoxicol. 2003 Aug;25(3):397-408.	
		MÉNEZ et al., Comparison of the "toxic" and antigenic regions in toxin alpha isolated from Naja nigricollis venom. Toxicon. 1982;20(1):95-103.	
		MÉNEZ, Molecular immunology of snake toxins. Pharmacol Ther. 1985;30(1):91-113.	
		MG-MG-THWIN et al., Relationship of administered dose to blood venom levels in mice following experimental envenomation by Russell's viper (Vipera russelli) venom. Toxicon. 1985;23(1):43-52.	
		MORAIS et al., Snake antivenoms from hyperimmunized horses: comparison of the antivenom activity and biological properties of their whole IgG and F(ab') <sub>2</sub> fragments. Toxicon. 1994 Jun;32(6):725-34.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

# EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 06/659,629, filed October 9, 1984 (now issued Patent No. 4,849,352), and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

FORM PTO-1449/A and B (modified PTO/SB/08)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 08/405,454	ATTY. DOCKET NO.: P0786.70000US05
				FILING DATE: March 15, 1995	CONFIRMATION NO.:
				APPLICANT: John B. Sullivan et al.	
				GROUP ART UNIT: 1644	EXAMINER: R. B. Schwadron
Sheet	4	of	5		

*	NISONOFF, Enzymatic digestion of rabbit gamma globulin and antibody and chromatography of digestion products. <i>Methods Med Res.</i> 1964;10:134-41.
	OFFERMAN et al., Crotaline Fab antivenom for the treatment of children with rattlesnake envenomation. <i>Pediatrics.</i> 2002 Nov;110(5):968-71.
*	OTTEN, Antivenin therapy in the emergency department. <i>Am J Emerg Med.</i> 1983 Jul;1(1):83-93
	OURTH et al., Neutralization of tetanus toxin by human and rabbit immunoglobulin classes and subunits. <i>Immunology.</i> 1977 Dec;33(6):807-15.
	OWNBY et al., Levels of therapeutic antivenin and venom in a human snakebite victim. <i>South Med J.</i> 1996 Aug;89(8):803-6.
	PIZON et al., Safety and efficacy of Crotalidae Polyvalent Immune Fab in pediatric crotaline envenomations. <i>Acad Emerg Med.</i> 2007 Apr;14(4):373-6. Epub 2007 Feb 12.
	REID, Adder bites in Britain. <i>Br Med J.</i> 1976 Jul 17;2(6028):153-6.
	RIVIÈRE et al., Absorption and elimination of viper venom after antivenom administration. <i>J Pharmacol Exp Ther.</i> 1998 May;285(2):490-5.
	RUSSELL, Ch. 26: Toxic effects of animal toxins. In Casarett and Doull's <i>Toxicology</i> , 5 <sup>th</sup> Ed. 1996:801-39.
	RUSSELL, Snake venom immunology: historical and practical considerations. <i>J Toxicol Rev.</i> 1988;7(1):1-82.
	SALWA et al., Efficacy of IgG, Fab, and F(ab') fragments of horse antivenom in the treatment of local symptoms after <i>Cerastes cerastes</i> (Egyptian snake) bite. <i>Af J Biotechnol.</i> July 2003;2(7):189-93.
	SÁNCHEZ et al., Cross reactivity of three antivenoms against North American snake venoms. <i>Toxicon.</i> 2003 Mar 1;41(3):315-20.
	SCHAEFFER et al., Enzyme-linked immunosorbant assay (ELISA) of size-selected crotalid venom antigens by Wyeth's polyvalent antivenom. <i>Toxicon.</i> 1988;26(1):67-76.
	SCHOTTLER, Problems of antivenin standardization. <i>Bull World Health Organ.</i> 1952;5(3):293-320.
	SCHOTTLER, Reference toxins for antivenin standardization. <i>Bull World Health Organ.</i> 1958;19(2):341-61.
	SEGER et al., Treatment of US crotalidae bites: comparisons of serum and globulin-based polyvalent and antigen-binding fragment antivenins. <i>Toxicol Rev.</i> 2005;24(4):217-27.
	SEIFERT et al., Recurrence phenomena after immunoglobulin therapy for snake envenomations: Part 1. Pharmacokinetics and pharmacodynamics of immunoglobulin antivenoms and related antibodies. <i>Ann Emerg Med.</i> 2001 Feb;37(2):189-95.
	SJOSTROM et al., A comparison of ovine and equine antivenoms. <i>Toxicon.</i> 1994 Apr;32(4):427-33.
	SMITH et al., Ability of polyvalent (Crotalidae) antivenin to neutralize myonecrosis, hemorrhage and lethality induced by timber rattlesnake ( <i>Crotalus horridus horridus</i> ) venom. <i>Toxicon.</i> 1985;23(3):409-24
	SMITH et al., Treatment of life-threatening digitalis intoxication with digoxin-specific Fab antibody fragments: experience in 26 cases. <i>N Engl J Med.</i> 1982 Nov 25;307(22):1357-62.
	SORKINE et al., Comparison of F(ab') and Fab efficiency on plasma extravasation induced by Viper aspis venom. <i>Toxicon.</i> 1995;33(3):259. Abstract.

EXAMINER:	DATE CONSIDERED:
-----------	------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 06/659,629, filed October 9, 1984 (now issued Patent No. 4,849,352), and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

<b>FORM PTO-1449/A and B (modified PTO/SB/08)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 08/405,454	ATTY. DOCKET NO.: P0786.70000US05
				FILING DATE: March 15, 1995	CONFIRMATION NO.:
				APPLICANT: John B. Sullivan et al.	
				GROUP ART UNIT: 1644	EXAMINER: R. B. Schwadron
Sheet	5	of	5		

	SU et al., The presynaptic neuromuscular blocking effect and phospholipase A2 activity of textilotoxin, a potent toxin isolated from the venom of the Australian brown snake, Pseudonaja textilis. Toxicon. 1983;21(1):143-51.	
	SULLIVAN et al., Isolation, quantitation, and subclassing of IgG antibody to Crotalidae venom by affinity chromatography and protein electrophoresis. Toxicon. 1983;21(Suppl. 3):429-32.	
	SULLIVAN, In search of a better snake trap. Wilderness Environ Med. 1999 Autumn;10(3):140-1.	
	SULLIVAN, Past, present, and future immunotherapy of snake venom poisoning. Ann Emerg Med. Sept. 1987;16(9):938-44.	
	SULLIVAN, Prevention and treatment of snakebite. Letter to the Editor. Ann Emerg Med. March 1984;13(3):215-16.	
	THEAKSTON et al., Antivenoms: a list of hyperimmune sera currently available for the treatment of envenoming by bites and stings. Toxicon. 1991;29(12):1419-70.	
	THEAKSTON et al., Report of a WHO workshop on the standardization and control of antivenoms. Toxicon. 2003 Apr;41(5):541-57.	
	TIMMERMAN et al., Comparative studies on the effectiveness of an antivenin and its fractions. Toxicon. 1969 May;6(4):311-4.	
	TIMSINA et al., Digoxin-specific Fab fragments impair renal function in the rabbit. J Pharm Pharmacol. 1992 Oct;44(10):867-9.	
	TRINH et al., Use of CroFab antivenin in the management of a very young pediatric copperhead envenomation. J Emerg Med. 2005 Aug;29(2):159-62.	
	WARRELL, Venom and antivenom. Saudi Med J. 1997;18(5):447-52.	
	WENGER et al., Treatment of 63 severely digitalis-toxic patients with digoxin-specific antibody fragments. J Am Coll Cardiol. 1985 May;5(5 Suppl A):118A-123A.	
	WILSON, Repeated administrations of crotalid Fab antivenin in the same patient. Am J Emerg Med. 2002 Oct;20(6):572.	
	WINGERT et al., Rattlesnake bites in southern California and rationale for recommended treatment. West J Med. 1988 Jan;148(1):37-44.	
	ZUCKER et al., Fab fragments of digoxin-specific antibodies used to reverse ventricular fibrillation induced by digoxin ingestion in a child. Pediatrics. 1982 Sep;70(3):468-71.	

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 06/659,629, filed October 9, 1984 (now issued Patent No. 4,849,352), and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

EXAMINER:	DATE CONSIDERED:
-----------	------------------

# EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 06/659,629, filed October 9, 1984 (now issued Patent No. 4,849,352), and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).